Patented Medicine Prices Review Board

Since 1987

PMPRB NEWSletter

Volume 15, Issue No. 4, October 2011

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Board Members

Chairperson:

Mary Catherine Lindberg, BSP

Vice-Chairperson:

Dr. Mitchell Levine

Members:

Tim Armstrong
QC, O. Ont.

Anne Warner La Forest
LLB, LLM

Since our last issue...

Our recent key events

August 10:	Michelle Boudreau presented a webinar and led a discussion for the Global Health Economics Association and CER Forum 2011: *Pharma IQ*.
September 8:	The HDAP held its quarterly meeting.
September 9:	Mary Catherine Lindberg accepted a Voluntary Compliance Undertaking (VCU) submitted by Eli Lilly Canada Inc. regarding the price of the patented medicine Effient.
September 13:	Michelle Boudreau met with the Board of Directors of Rx&D.
September 21:	Mary Catherine Lindberg spoke at the Canadian Association for Healthcare Reimbursement (CAHR) conference: *Healthcare and Biopharmaceuticals in Canada – A Federal Perspective*.
September 22:	Mary Catherine Lindberg accepted a Voluntary Compliance Undertaking (VCU) submitted by Merck Canada Inc. regarding the price of the patented medicine Nasonex.
September 29:	Michelle Boudreau met with Jim Keon, President of the Canadian Generic Pharmaceutical Association (CGPA) and with its Director of Federal Government Relations, Jodi Cox.
September 30:	Three new NPDUIS reports were released. For more information, see the article in this issue.
September 30:	The PMPRB launched its updated website.
October 3–6:	Mary Catherine Lindberg and Michelle Boudreau met with senior provincial health officials in Manitoba, Ontario and Nova Scotia, as well as with representatives of the Canadian Life and Health Insurance Association Inc. (CLHIA).
October 12:	Michelle Boudreau met with the President of the Health Council of Canada.
October 13–14:	The Board held its quarterly meeting.
October 14:	Mary Catherine Lindberg accepted a Voluntary Compliance Undertaking (VCU) submitted by Merck Canada Inc. regarding the price of the patented medicine Orgalutran.
October 21:	Michelle Boudreau met with provincial and territorial drug plan managers and policy ADMs of the Drug Policy Advisory Committee, Canadian Agency for Drugs and Technologies in Health (CADTH).
October 27:	The NPDUIS Steering Committee meeting was held in Ottawa.
October 27–29:	Mary Catherine Lindberg participated in the Canadian Health Policy Assembly in Banff.

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If you wish to know more about the PMPRB, please contact us at our toll-free number, 1-877-861-2350, or consult our website.

The PMPRB is an independent quasi-judicial body with a dual mandate.
Regulatory: to ensure that prices at which patentees sell their patented medicines in Canada are not excessive; and
Reporting: to report on pharmaceutical trends of all medicines and on R&D spending by patentees.

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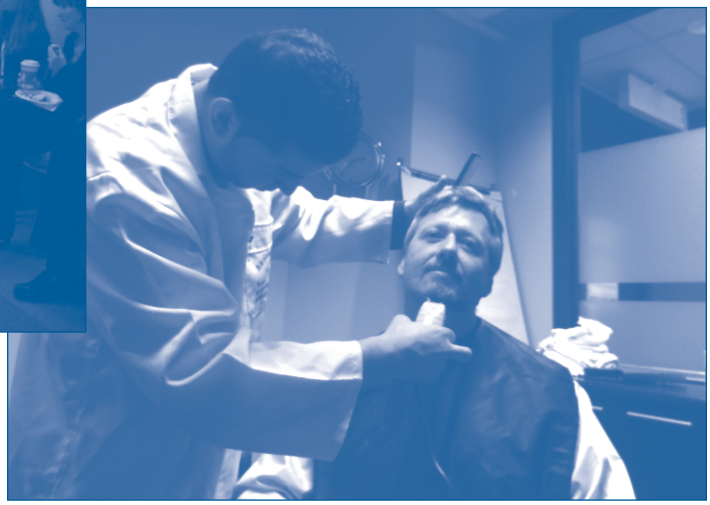
October 31: The PMPRB published the first issue in its new series ***Analysis Briefs***. This series features short summaries of analysis work produced by the PMPRB. Visit the PMPRB website to link to the first title: *Trends in Sales of Patented Drug Products* at Publications/Analysis Briefs.

PMPRB speeches and presentations are available on the website at News and Events/Speech Series. ■

The PMPRB held its yearly breakfast! Funds raised go to the Government of Canada Workplace Charitable Campaign.



The PMPRB officially launched its Movember campaign to help raise awareness for finding a cure for prostate cancer.

Senior Staff

Executive Director:
Michelle Boudreau

Director, Regulatory Affairs and Outreach:
Ginette Tognet

Director, Policy and Economic Analysis:
Gregory Gillepsie

Director, Corporate Services:
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Director, Board Secretariat and Communications:
Sylvie Dupont

General Counsel:
Martine Richard

Announcement: *NEWSletter* – Online access only beginning in January 2012

Beginning with the January 2012 issue, the PMPRB *NEWSletter* will no longer be available in print copy.

By publishing the *NEWSletter* only in electronic format (HTML and PDF), the PMPRB will save on printing and distribution costs and will benefit the environment by reducing its carbon footprint.

We welcome you to sign up for the e-bulletin alert on our home page. You will receive an email notification with a link to the full electronic content upon publication.

The PMPRB has always strived to maintain a balance between fiscal and environmental responsibility and accessibility. Although we will not be offering ongoing print subscriptions, if you require a single printed copy of any of our publications, please contact us by email at pmprb@pmprb-cepmb.gc.ca or by phone at 613-952-3300 (toll free: 1-877-861-2350; TYY: 613-957-4373). Note that we will still be providing print copies of our 2011 Annual Report. ■

News from the Chairperson

Mary Catherine Lindberg, Chairperson

The PMPRB's agenda over the last quarter has been full. In addition to going through a core control audit, holding a strategic planning session and enhancing our website, our organization met with several stakeholder groups, including selected provincial health officials.

As healthcare needs in Canada become more acute, the PMPRB's consumer protection role becomes more important. To that end, we are expanding our engagement with stakeholders, gathering the most up-to-date information to better inform our strategic plans and policies and re-orient our priorities, all in the context of our mandate to ensure that prices of patented medicines are not excessive.

Our ongoing exchanges with diverse groups, including industry representatives, provincial health officials, patient-advocacy groups and healthcare professionals, ensure that we continue to be involved in knowledge dissemination. Furthermore, the wide range of feedback that we receive enables us to strengthen our contribution to consumers and the healthcare system.

As we continue to re-evaluate and renew our processes, the Board remains committed to predictability, fairness and transparency. ■

Mary Catherine Lindberg

Remembering Martin Mason

It was with profound sadness that we learned of Martin Mason's passing last June.

A highly talented lawyer, an effective counsel and thoughtful advocate, Martin Mason had appeared before courts and tribunals such as the Patented Medicine Prices Review Board and had pleaded before the Supreme Court. He practiced in the areas of administrative law, constitutional law and civil litigation. Martin had also served as adjunct professor at the University of Ottawa, where he taught constitutional law.

His absence will be long felt by his peers and decision-makers alike who looked to Martin for his keen ability to present a clear analysis of complex issues.

We offer our heartfelt condolences to Martin's family and friends. He will indeed be greatly missed. ■

Comings and Goings

Orlando Manti recently retired from the Federal Public Service. Orlando worked for the PMPRB for the last 12 years of his professional career, most recently as Manager, Economic Analysis, for the Policy and Economic Analysis Branch. We extend our thanks to him and wish him good luck in his new endeavours.

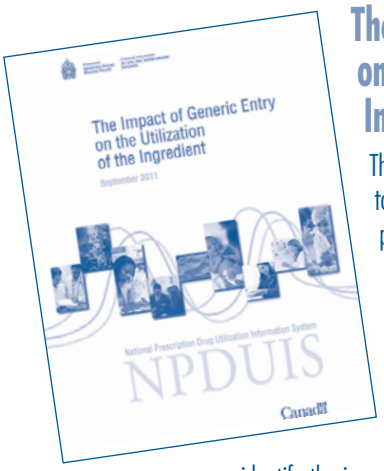
Our best wishes go out to Kevin Crombie, who recently left the PMPRB to take on new challenges as a Senior Communications Advisor at Health Canada, and to Patricia Hum and Anne Tardif, who recently left on maternity leave.

We are pleased to welcome Julia Barss to the PMPRB as a lawyer for Legal Services. Julia joined the PMPRB from the Department of Justice. We would also like to welcome back Elena Lungu, who recently returned from maternity leave. Elena is currently the Acting Manager of the NPDUIS program. ■

NPDUIS – Release of Analytical Reports

Three new analytical reports were published by the PMPRB on September 30, 2011. The topics covered in the reports relate to the impact generic competition has on the utilization of drug products; the cost drivers of recent increases in the amount Canada's public drug plans reimburse for dispensing fees; and further analysis related to international generic drug prices.

A brief description of each of the reports follows.

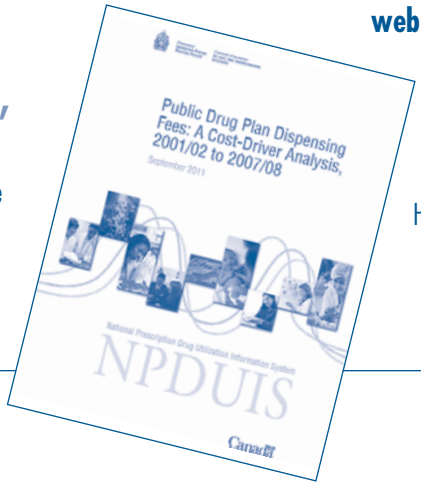


The Impact of Generic Entry on the Utilization of the Ingredient

The loss of patent protection for a number of top-selling drug products in recent years promises to offer real cost savings for Canada's public drug plans. However, should utilization shift away from these established medications to newer, potentially more expensive alternatives, the extent of the savings may diminish. The study analyzed public drug plan data to identify the impact of loss of patent protection on drug utilization. The report concludes that post generic entry, the utilization of the ingredient followed the same trend established by the brand name product prior to the loss of market exclusivity. In most cases, any short- or long-term shift in utilization from established to newer medications could not be directly and solely attributable to generic entry.

Public Drug Plan Dispensing Fees: A Cost-Driver Analysis, 2001/02 to 2007/08

In recent years, public drug plan expenditure on dispensing fees has increased rapidly for several Canadian public drug plans, with some experiencing double-digit annual growth rates. This report identifies and then quantifies the factors driving dispensing fee expenditure from 2001/02 to 2007/08. The growth in the number of prescriptions, changes in prescription length and the average fee reimbursed per prescription were identified as the primary drivers behind the reported dispensing fee increases.



Generic Drugs in Canada: International Price Comparisons and Potential Cost Savings

This report is a follow-up to the series of studies prepared by the PMPRB analyzing the international prices of generic drug products. The study compares the 2008 prices of prescription generic drug products in Canada to prices in other industrialized countries. It also estimates the potential savings that might be realized by public drug plans if Canadian generic prices were brought into line with foreign prices. Based on the 2008 data, the study estimates that the potential cost savings for Canada's public drug plans would range between 40–50%. Recent changes made to the pricing structure for generic drugs in the past several months by several provincial drug plans are not captured by the data.

NPDUIS reports can be downloaded from the PMPRB website at NPDUIS/Recent Publications

Through the NPDUIS initiative, the PMPRB provides critical analyses of price, utilization and cost trends in Canada to support drug plan policy decision making. NPDUIS is a partnership between the PMPRB and federal, provincial, territorial governments and the Canadian Institute for Health Information. ■

New Patented Medicines Reported to the PMPRB

New drug products first sold in 2011 will be reviewed based on the Guidelines implemented on January 1, 2010. As of September 30, 2011, a total of 85 new drug products (DINs) were reported to the PMPRB (representing 49 medicines). Information on these patented drug products can be found on the PMPRB website at Regulating Prices/Price Review/Status of New Patented Medicines by Year/2011. ■

Summary Report on Patented Drugs

Work is continuing on developing the new reports in a user-friendly Web application. The PMPRB is planning to launch the new format on the website in January 2012.

This new format will include:

- Information on the new drug product
- Level of therapeutic improvement (including rationale for breakthough, substantial improvement and moderate improvement, information on evidence where secondary factors considered for moderate improvement)
- Comparators and comparable dosage regimens
- Comparator countries
- Maximum average potential price

Look for our new reports on our website under Regulating Prices/Price Review. ■

Drug Products Not Normally Reviewed by the Human Drug Advisory Panel – Deadlines for Submissions to HDAP

The Human Drug Advisory Panel (HDAP) provides expertise and advice to Board Staff in conducting the scientific review. HDAP performs the following functions:

- Reviews and evaluates scientific information
- Considers advice from other experts (when deemed necessary)
- Recommends the level of therapeutic improvement of the new patented drug product and identifies drug products for comparison purposes and dosage regimens where possible
- Identifies significant uncertainties in the evidence that may affect the analysis on which its recommendations are based

In general, all new patented drug products are referred to the HDAP. However, the *Compendium of Policies, Guidelines and Procedures* specifies that the following drug products will not be reviewed by HDAP unless the patentee files a submission claiming therapeutic improvement:

- The new patented drug product represents a new DIN of an existing dosage form of an existing drug product, or a new DIN of another dosage form of the existing drug product that is comparable to the existing dosage form as per Schedule 2 and has the same indication or use as the existing DIN; or
- The new patented drug product is a combination drug product, the individual components of which are sold in Canada and have the same indication or use; or
- The new patented generic drug product is considered by Health Canada to be bioequivalent to the reference brand drug product sold in Canada; or
- The new patented generic drug product is a licensed version of an existing brand drug product sold in Canada.

A patentee must submit a copy of the product monograph or information similar to that contained in a product monograph about three and a half (3.5) months prior to the particular HDAP meeting. A patentee wishing to make a submission with respect to the level of therapeutic improvement, the selection of drug products and dosage regimens to be used for comparison purpose, must do so no later than 10 weeks prior to the particular HDAP meeting. Although this submission is due no later than 10 weeks prior to the particular HDAP meeting, a patentee is requested to indicate whether it is intending to make such a submission at the same time as the product monograph, or information similar to that contained in the product monograph, is filed.

In the past year, there have been many occasions when a patentee has indicated in writing, when it files its product monograph or information similar to that contained in a product monograph, that it intended to make a submission claiming therapeutic advantage for the drug products listed above for review by the HDAP. However, the patentee did not make a moderate improvement submission. In these cases, the result was that considerable effort was expended in terms of scientific and financial resources, as the scientific process begins as soon as the product monograph (or information similar to that contained in a product monograph) is filed.

Consequently, a patentee wishing to make a submission with respect to the level of therapeutic improvement, the selection of drug products and dosage regimens to be used for comparison purposes for the drug products listed above (i.e., those that would not otherwise be reviewed by the HDAP) must make its submission at the same time as it files its product monograph or information similar to that contained in a product monograph.

The table following provides the submission deadlines for the meetings of the HDAP in 2012.

HDAP Meeting/ Conference Call	Information (including information for drug products not normally reviewed by HDAP)	Deadline
February 6, 2012	• 1 copy of product monograph or information similar to that contained in a product monograph (if drug product has not yet been approved for sale in Canada) and the proposed level of therapeutic improvement AND 10 copies of patentee submission for drug products listed in section C.3.2 of the *Compendium of Policies, Guidelines and Procedures* (Guidelines)	• **October 24, 2011**
	• 10 copies of patentee submission (for drug products that are not listed in section C.3.2 of the Guidelines)	• **November 24, 2011**
May 7, 2012	• 1 copy of product monograph or information similar to that contained in a product monograph (if drug product has not yet been approved for sale in Canada) and the proposed level of therapeutic improvement AND 10 copies of patentee submission for drug products listed in section C.3.2 of the Guidelines	• **January 24, 2012**
	• 10 copies of patentee submission (for drug products that are not listed in section C.3.2 of the Guidelines)	• **February 24, 2012**
September 24, 2012	• 1 copy of product monograph or information similar to that contained in a product monograph (if drug product has not yet been approved for sale in Canada) and the proposed level of therapeutic improvement AND 10 copies of patentee submission for drug products listed in section C.3.2 of the Guidelines	• **June 11, 2012**
	• 10 copies of patentee submission (for drug products that are not listed in section C.3.2 of the Guidelines)	• **July 11, 2012**
November 5, 2012	• 1 copy of product monograph or information similar to that contained in a product monograph (if drug product has not yet been approved for sale in Canada) and the proposed level of therapeutic improvement AND 10 copies of patentee submission for drug products listed in section C.3.2 of the Guidelines	• **July 23, 2012**
	• 10 copies of patentee submission (for drug products that are not listed in section C.3.2 of the Guidelines)	• **August 23, 2012** ■

Updates to the PMPRB Website

In an effort to better serve its stakeholders the PMPRB has revamped its website. Content has been reorganized and streamlined to provide added context and a more user-friendly environment.

As a result of the overhaul of the website's architecture, content may no longer be located in the same place as it was previously. Please make sure to update any bookmarks you may have and feel free to contact us if you cannot locate the information you are looking for. We can be reached at pmprb@pmprb-cepmb.gc.ca.

Take some time to browse the website and provide any feedback you may have. We look forward to hearing from you. ■

Voluntary Compliance Undertakings

A Voluntary Compliance Undertaking (VCU) is a written undertaking by a patentee to adjust its price to conform to the Board's Guidelines. Under the Guidelines, patentees are given an opportunity to submit a VCU when Board Staff concludes, following an investigation, that the price set forth by the patentee for a patented drug product sold in Canada appears to have exceeded the Guidelines. A VCU can also be submitted by a patentee after a Notice of Hearing is issued.

In the third quarter, four VCUs were accepted for the patented medicines Sinemet CR, Effient, Nasonex and Orgalutran.

Sinemet CR, Bristol-Myers Squibb Canada Co.

On July 10, 2011, the Chairperson of the Board approved a VCU submitted by Bristol-Myers Squibb Canada Co. regarding the price of Sinemet CR. Under the terms of the VCU, Bristol-Myers offset the cumulative excess revenues received from 2009 to June 1, 2010, in the amount of $64,442.01 by making a payment to the Government of Canada.

Sinemet CR is indicated for the treatment of Parkinson's disease.

Effient, Eli Lilly Canada Inc.

On September 9, 2011, the Chairperson of the Board approved a VCU submitted by Eli Lilly Canada Inc. regarding the price of Effient. Under the terms of the VCU, Eli Lilly offset the cumulative excess revenues received from May 17, 2010, to June 30, 2010, by making a payment of $4,618.51 to the Government of Canada.

Effient (prasugrel) is indicated for co-administration with acetylsalicylic acid (ASA) for early and long-term secondary prevention of atherothrombotic events in patients with acute coronary syndrome (ACS).

Nasonex, Merck Canada Inc.

On September 22, 2011, the Chairperson of the Board approved a VCU submitted by Merck Canada Inc. regarding the price of Nasonex. As part of the terms of the VCU, Merck Canada Inc. is to reduce the price of Nasonex no later than November 3, 2011, so that it does not exceed the 2011 N-NEAP of $0.1986. Merck is also to offset cumulative excess revenues received from January 1, 2010, to December 31, 2010, by making a payment to the Government of Canada in the amount of $165,098.43. As well, in order to offset any excess revenues received during the period of January 1, 2011, to the date of reduction of the price of Nasonex, Merck is to make a payment, no later than February 29, 2012, in the amount of the excess revenues, as calculated by Board Staff, received as a result of selling Nasonex at a price in excess of the 2011 N-NEAP.

Nasonex (mometasone furoate 0.05 mg/dose) is indicated:

- For use in adults, adolescents, and children between the ages of 3 and 11 years to treat the symptoms of seasonal or perennial allergic rhinitis
- For use in adults and children 12 years of age and older as adjunctive treatment to antibiotics in acute episodes of rhinosinusitis, where signs or symptoms of bacterial infection are present
- For use in adults and children 12 years of age and older in the treatment of symptoms associated with mild to moderate uncomplicated acute rhinosinusitis where signs or symptoms of bacterial infection are not present
- For the treatment of nasal polyps in adult patients 18 years of age or older

Orgalutran, Merck Canada Inc.

On October 14, 2011, the Chairperson of the Board approved a VCU submitted by Merck Canada Inc. regarding the price of Orgalutran. Under the terms of the VCU, Merck Canada Inc. offset cumulative excess revenues received from August 2002 to December 31, 2010, by making a payment to the Government of Canada in the amount of $393,558.85 no later than November 18, 2011. As well, in order to offset any excess revenues received during the period of January 1, 2011, to December 31, 2011, Merck is to make a payment, no later than February 29, 2012, in the amount of the excess revenues, as calculated by Board Staff, received as a result of selling Orgalutran at a price in excess of the 2011 N-NEAP.

Orgalutran (ganirelix acetate) is a gonadotropin-releasing hormone (GNRH) antagonist that is indicated for the prevention of premature luteinizing hormone (LH) surges in women undergoing controlled ovarian hyperstimulation (COH). It is supplied in 250 mcg prefilled syringes for subcutaneous injection.

The prices of these drug products are to remain within the Guidelines in all future periods in which they are under the PMPRB's jurisdiction.

VCUs are available on the PMPRB website at Voluntary Compliance Undertakings. ■

Hearings – Update

The PMPRB's regulatory mandate is to ensure that prices charged by patentees for their patented medicines sold in Canada are not excessive.

In the event that the price of a patented medicine appears to be excessive, the Board can hold a public hearing and, if it finds that the price is excessive, it may issue an order to reduce the price and to offset revenues received as a result of excessive prices. Board decisions are subject to judicial review in the Federal Court of Canada.

Status of Board Proceedings

Patented Drug Product	Indication / Use	Patentee	Date of Notice of Hearing	Status
Apo-Salvent CFC-Free	Relief of chest tightness and wheezing caused by spasms or narrowing in the small air passages of the lungs	Apotex Inc.	July 8, 2008	**Ongoing**
Copaxone – Redetermination	Use in ambulatory patients with relapsing-remitting multiple sclerosis to reduce the frequency of relapses	Teva Neuroscience G.P.-S.E.N.C. (now Teva Canada)	New panel struck February 2010	**Board decision pending**
Pentacel and Quadracel	Pentacel is a co-marketing of two licensed vaccines: Act-HIB (the lyophilized Haemophilus b Conjugate Vaccine (Tetanus Protein-Conjugate) to be reconstituted with Quadracel. It is indicated for the routine immunization of all children between 2 and 59 months of age against diphtheria, tetanus, whooping cough (pertussis), poliomyelitis and *Haemophilus influenzae type b disease*. Quadracel is a Component Pertussis Vaccine and Diphtheria and Tetanus Toxoids Adsorbed combined with Inactivated Poliomyelitis Vaccine. It is indicated for the primary immunization of infants, at or above the age of 2 months, and as a booster in children up to their 7th birthday against diphtheria, tetanus, whooping cough (pertussis) and poliomyelitis.	sanofi pasteur Limited	March 27, 2007	**Federal Court decision: July 12, 2011** **Matter (remedy) returned to the Hearing Panel for reconsideration**
ratio-Salbutamol HFA	Relief of chest tightness and wheezing caused by spasms or narrowing in the small air passages of the lungs	ratiopharm Inc. (now Teva Canada)	July 18, 2008	**Federal Court Judicial Review Application filed June 27, 2011** **Federal Court Hearing date to be announced**

Patentee	Issue	Date of Notice of Application	Status
Apotex Inc.	Failure to file (jurisdiction)	March 3, 2008	**Ongoing**
ratiopharm Inc. (now Teva Canada)	Failure to file (jurisdiction)	August 28, 2008	**Board Decision: June 30, 2011** **Amended: October 17, 2011**
Sandoz Canada Inc.	Failure to file (jurisdiction)	March 8, 2010	**Board decision pending**

Board decisions and orders are available on the PMPRB website at Hearings and Decisions. ■

Summary of October 13–14 Board Meeting

At its October meeting, the Board held a strategic planning session during which it discussed the current pharmaceutical environment, the PMPRB's regulatory framework and strategic direction, as well upcoming activities in the context of the Board's stakeholder engagement.

In addition, the Board met with the President and CEO of the British Columbia Gastrointestinal Society and discussed issues of stakeholder engagement. Board members were briefed on the core value audit of the PMPRB as performed by the Office of the Comptroller General; PMRPB-related submissions to the Prime Minister's Red Tape Reduction Commission; ongoing monitoring and evaluation of the major changes in the Guidelines; and on analyses conducted in the context of the National Prescription Drug Utilization Information System (NPDUIS) and the upcoming NPDUIS Steering Committee meeting.

The Board's next meeting is scheduled for December 8 and 9, 2011.

For additional information, please contact the Director, Board Secretariat and Communications, at 1-877-861-2350 or 613-954-8299 or at sylvie.dupont@pmprb-cepmb.gc.ca.

Summaries of Board meetings are available on the PMPRB website at About PMPRB. ■

Upcoming Events

November

November 1–4:
Mary Catherine Lindberg and Michelle Boudreau to meet with senior provincial health officials and other healthcare representatives in British Columbia and Alberta

November 2–4:
7th Annual Health Insurance Strategic Forum, Cambridge, Ontario

November 7:
HDAP meeting

November 5–8:
Dr. Mitchell Levine and Ginette Tognet to attend International Society Pharmacoeconomics and Outcomes Research (ISPOR) 14th Annual European Congress in Madrid, Spain

November 15–16:
Michelle Boudreau to speak at the 10th Annual Market Access Summit in Toronto

December

December 8–9:
Quarterly Board meeting

2012 – January

January 30:
Deadline for Patentees to file Form 2

March

March 1:
Deadline for Patentees to file Form 3

March 20-23:
Michelle Boudreau will speak at the Pharma Pricing & Market Access Outlook Europe 2012 Conference in London, UK

For all Upcoming Events see the Calendar of Events on the PMPRB website at News and Events ■

Subscription Information and Services

The PMPRB *NEWSletter* is a free quarterly publication available electronically on the Web. For immediate access to timely information, readers are invited to sign up for the email alert service.

E-bulletin alert: sign up for an email alert and you will be automatically notified as soon as the *NEWSletter* is published, with a link to the full electronic content. In addition, relevant news items and announcements will be sent to you directly upon their release.

To subscribe to this service, click on the link at the bottom of the PMPRB home page at www.pmprb-cepmb.gc.ca.

Readers are reminded to update their contact information when required by accessing the change of address link at the bottom of the PMPRB home page.

Please note that beginning January 2012, paper copies of publications will be made available by request only. ■

We Welcome Your Feedback

We want to hear from you. If you have any comments or suggestions for topics you wish to see covered in the *NEWSletter*, or if you would like more information on the PMPRB, contact us at:

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